REMARKS/ARGUMENTS

Applicants acknowledge the Notice of Appeal filed on May 12, 2006, however, in an effort to efficiently resolve the outstanding issues, Applicants file a Request for Continued Examination (RCE) herein to allow the Examiner additional time for reconsideration.

Claim Status

Claim 1 is currently under examination. Claims 1 and 39-46 remain pending in the instant application.

Claims 2-38 were cancelled in a previous response (filed on June 9, 2003). Claims 39-46 are withdrawn from consideration. It is understood that claims 39-46, drawn to the non-elected invention, will remain pending, albeit withdrawn from consideration on the merits at this time. If the examined claim of the Group I invention is deemed to be allowable, rejoinder of the remaining claims (39-46) in accordance with the decision in *In re Ochiai* is respectfully requested; since the remaining claims (39-46) are limited to the use of the biopolymer marker of claim 1 (the examined claim of the elected Group I invention).

Request for Rejoining of Claims

Considering that claims 39-46 are limited to the use of SEQ ID NO:1 a search of these claims would encompass this specific sequence. The instant application is related in claim format to several other applications, both pending and issued, of which serial number 09/846,352 is exemplary. In an effort to maintain equivalent scope in all of these applications, Applicants respectfully request that the Examiner consider rejoining claims 39-46 in the instant application, which are currently drawn to non-elected Groups, with claim 1 of the elected Group under the decision in *In re Ochiai* (MPEP 2116.01), upon the Examiner's determination that claim 1 of the elected invention is allowable and in light of the overlapping search. If the biopolymer marker of SEQ ID NO:1 is found to be novel, methods and kits limited to its use should also be found novel.

Outstanding Rejections

Claim 1, as presented on October 13, 2005, remains rejected under 35 USC 101 because the claimed invention allegedly has no apparent or disclosed specific and substantial credible utility.

Claim 1 also remains rejected under 35 USC 112, first paragraph. The Examiner asserts that since the claimed invention is not supported by either a clear asserted utility or a well

established utility, one of skill in the art would clearly not know how to use the claimed invention.

Applicants respectfully disagree with all of the Examiner's assertions.

Claim 1, as currently under examination, recites an isolated biopolymer marker consisting of amino acid residues 2-18 of SEQ ID NO:1 which evidences a link to Alzheimer's disease. SEQ ID NO:1 has been identified as a fragment of apolipoprotein J precursor having a molecular weight of 1874 daltons and was found to be differentially expressed in Alzheimer's disease versus age-matched controls(see, for example, page 8-10 of the Response filed on February 9, 2006). This differential expression is clearly shown in Figure 1 (see the Declaration under 37 CFR 1.132 filed on February 9, 2006, especially item #4 and the attached figure) and links the claimed peptide to Alzheimer's disease.

The Examiner does not dispute the differential expression of the claimed peptide, however, she does not consider differential expression sufficient to establish utility of the peptide as a marker. Additionally, the Examiner appears to believe that since other peptides have also been identified from Band C1, Applicants can not be certain that the claimed peptide is the peptide exhibiting the differential expression. Thus, the Examiner concludes that Applicants' asserted utility is not credible.

The method of identification of the claimed peptide as a marker for Alzheimer's disease was clearly disclosed in the specification as originally filed and furthermore was also explained extensively at pages 11-14 of the Response filed on February 9, 2006.

According to the method of the invention, the criteria for evaluation is the identification of specific ions from the bands in the gel and not the appearance of the band itself; i.e. bands are initially selected for further analysis based on differential expression observed in gels but peptides contained within the bands are ultimately identified by mass spectrometry, and not by gel electrophoresis alone. A hypothetical example may serve to clarify. For example, a researcher has found that Band X is differentially expressed between a lung cancer patient and a patient who was determined to be normal with regard to lung cancer. In hope of identifying potential markers for lung cancer, the researcher subjects Band X to mass spectrometry and obtains three distinct mass spectral profiles. Two of these mass spectral profiles match to known proteins, Protein A and Protein B, which the researcher than identifies as potential markers for lung cancer. The fact that multiple peptides were identified from one band does not diminish the value of each of the peptides as markers since it is the mass spectral profile which is unique and not the band itself. If a

peptide is identified in a particular band, then it is present in that band regardless of the presence and/or absence of other peptides/proteins within the same band.

Where the asserted specific and substantial utility is not credible, a *prima facie* showing of no specific and substantial credible utility must establish that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the Applicant for the claimed invention (see MPEP 2107.02).

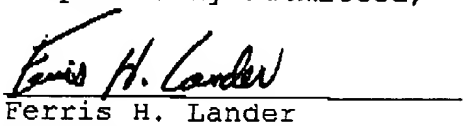
The Examiner has not provided any evidence or documentation supporting her opinion that one of skill in the art would not recognize the claimed peptide as linked to Alzheimer's disease. Thus, the Examiner has erred by requiring Applicants to meet a standard higher than is necessary to satisfy the utility requirement.

Accordingly, Applicants respectfully submit that the Examiner has failed to establish a proper *prima facie* showing of the lack of utility of the claimed invention and respectfully request that the rejection now be withdrawn.

CONCLUSION

In light of the foregoing remarks it is respectfully submitted that the Examiner will now find the claims of the application allowable. Favorable reconsideration of the application is courteously requested.

Respectfully submitted,



Ferris H. Lander
Registration # 43,377

McHale & Slavin, P.A.
2855 PGA Boulevard
Palm Beach Gardens, FL 33410
(561) 625-6575 (Voice)
(561) 625-6572 (Fax)
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